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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,942	07/21/2003	Marco Pappagallo	05986/100K504-US1	7691

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,942	PAPPAGALLO, MARCO	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on September 25, 2007 have been received and entered into the application.

Action Summary

The rejection of claims 1-3, 5- 9 and 11 under 35 U.S.C. 102(a) as being anticipated by Geusens et al. (2001) is being maintained for the reasons stated in the previous Office Action.

The rejection of claims 1, 4 and 10 under 35 U.S.C. 103(a) as being unpatentable over Urban et al. (2001) in view of Bader et al. is being maintained for the reasons stated in the previous Office Action.

Response to Arguments

Applicant's arguments filed September 25, 2007 have been fully considered but they are not persuasive. Applicant argues that patient described in Geusens has osteoporotic

vertebral compression while the present claims are directed to methods of treating "chronic spinal mechanical pain," which is expressly defined in the specification to exclude cancer pain and osteoporotic compression fracture pain and that the definition for the claim term "chronic spinal mechanical pain" provided in the specification can not be ignored. This is not persuasive because Applicant is reminded that the claims are interpreted in light of the specification; **limitations from the specification are not read into the claims**. See *In re Van Geuns*, 26, USPQ2d 1057 (Fed. Cir. 1993). See also *In re Morris*, 44, UPQ2d 1023, 1027-28 (Fed. Cir. 1997) (The court held that the PTO is not required, in the course of prosecution, to interpret claims in applications in the same manner as a court would interpret claims in an infringement suit). Therefore, given the **broadest and reasonable interpretation** of the instantly rejected claims under 35 U.S.C 102 rejection, drawn to "chronic spinal mechanical pain", the cited prior art clearly teaches each and every element recited in the claims. It is noted that claims 4 is not included in the 102 rejection. Accordingly, the rejection under 35 U.S.C. 102 made in the previous Office Action is deemed proper.

With regard to obviousness rejection, Applicant argues that Urban is limited to the treatment of bone cancer-induced pain that does not fall within the scope of the claim reciting the phrase "chronic spinal mechanical pain" which is expressly defined in the present specification excluding cancer pain that lasts for more than 12 weeks. This is not found persuasive because again, while the claims are interpreted in light of the specification, limitations from the specification are **not read into the claims**. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir.1993). In this case, Urban et

al. teach that zoledronate has antinociceptive effect in a novel rat model of bone cancer pain while Bader et al. teach the route of administration of zoledronate. Therefore, it would have been obvious to one of ordinary skill in the art to employ zoledronate in the treatment of pain via employment of route of administration taught by Bader et al. in order to achieve an expected benefit antinociceptive effect of zoledronate as taught by Urban et al. There is a reasonable expectation of success in treatment of pain including chronic back pain particularly cancer pain because Urban et al. particularly teaches treatment of pain involving cancer. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of August 6, 2007 is deemed proper, remains in force and is incorporated herein.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5- 9 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Geusens et al. (2001) of record.

Geusens et al. teach that an 18-year-old boy presented with extreme back pain as the result of multiple vertebral fractures was treated with intermittent intravenous bisphosphonate such as pamidronate. (abstract). Geusens et al. teach that intermittent IV infusions of pamidronate were given at dose of 30mg infusion, 300 mg in total over 9

month. (page 390 right-hand column first sentence originated from left-hand column, bottom). The boy progressively recovered from back pain and is now, at age 20, fully ambulant. (abstract).

The teaching from Geusens et al. that the boy suffered from vertebral fracture back pain encompasses Applicant's limitation of spinal mechanical pain because the term vertebral is referred to spinal column. With respect to the limitation of more than one dose is administered set forth in claim 2 is anticipated by the Geusens et al's teaching that the dose of pamidronate were given over total of 9 month. With respect to the limitation of single does set forth in claim 11 is anticipated by the Geusens et al's teaching because a single dose of 30mg per infusion was given at a time.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urban et al. (2001) in view of Bader et al, both of record.

Urban et al. teach that the bisphosphonate, zoledronate (30mcg/kg, s.c.) produced a significant anti-allodynic effect in rats. (abstract).

Urban et al. do not teach the intravenous administration of zoledronic acid for the treatment of pain.

Bader et al. report that bisphosphonates and their salts including zoledronate has been used as parenteral preparations for intravenous infusion and injection and preferably made available and utilized. (column 1, lines 14-26).

It would have been obvious to one of ordinary skill in the art to employ zoledronic acid for the treatment of pain in intravenous administration because zoledronic acids is well-known to be administered intravenously and preferably made available and utilized in parenteral infusion and injection formulations as taught by Bader et al. One would have been motivate do employ zoledronic acid in preferred parenteral preparations including intravenous injection in order to provide alternative parenteral preparations next to subcutaneous injectable taught by Urban. There would have been a reasonable expectation of successfully administering zoledronic acid intravenously for the treatment of pain because intravenous infusion and injection formulation of zoledronate are preferably made available to be utilized as reported by Bader et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Primary Examiner
Art Unit 1617

Jmk
November 21, 2007